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APPLICATION NO. FILING DAT		FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,411 08/20/2003		08/20/2003	Jean-Francois Riou	STO1004 US CIP	7926
5487	7590	07/26/2006	EXAMINER		INER
ROSS J. (	DEHLER		PERREIRA, MELISSA JEAN		
SANOFI-	AVENTSI	U.S. LLC			
1041 ROU	TE 202-20	6	ART UNIT	PAPER NUMBER	
MAIL CO	DE: D303A	A	1618		
BRIDGEV	VATER, N	IJ 08807	DATE MAILED: 07/26/2006		

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applicati	Application No.		Applicant(s)				
	Office Assis a Communication	10/644,4	11	RIOU ET AL.					
	Office Action Summary	Examine	r	Art Unit					
		Melissa F		1618					
Period fo	The MAILING DATE of this communication or Reply	n appears on th	e cover sheet with the c	orrespondence a	ddress				
WHIC - Exter after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR RECHEVER IS LONGER, FROM THE MAILING INSIGNS OF THE MAILING OF THE	G DATE OF TI FR 1.136(a). In no even. In. eriod will apply and we statute, cause the app	HIS COMMUNICATION ent, however, may a reply be timil expire SIX (6) MONTHS from slication to become ABANDONE	1. nely filed the mailing date of this D (35 U.S.C. § 133).					
Status									
1)	Responsive to communication(s) filed on 2	27 June 2006							
2a)□		This action is r	ion-final						
3)	· <del>-</del>		secution as to th	e merits is					
-,	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.								
Dispositi	on of Claims		,,						
		onligation							
•	Claim(s) 1-4 and 7 is/are pending in the application.								
	4a) Of the above claim(s) <u>5,6 and 8-12</u> is/are withdrawn from consideration.								
·	Claim(s) is/are allowed.								
-	Claim(s) <u>1-4 and 7</u> is/are rejected.								
	Claim(s) is/are objected to.								
8)	Claim(s) are subject to restriction as	na/or election r	equirement.						
Applicati	on Papers								
9)□	The specification is objected to by the Exar	miner.							
10)🛛	10)⊠ The drawing(s) filed on <u>20 August 2003</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.								
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
	Replacement drawing sheet(s) including the co	orrection is requir	ed if the drawing(s) is obj	ected to. See 37 C	FR 1.121(d).				
11)	The oath or declaration is objected to by the	e Examiner. N	ote the attached Office	Action or form P	TO-152.				
Priority u	ınder 35 U.S.C. § 119								
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>									
	e of References Cited (PTO-892)	on	Interview Summary Paper No(s)/Mail Da						
	e of Draftsperson's Patent Drawing Review (PTO-948 nation Disclosure Statement(s) (PTO-1449 or PTO/SE		5) Notice of Informal Page 1		O-152)				
	r No(s)/Mail Date	,	6) Other:		·				

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#### **DETAILED ACTION**

# Response to Arguments

Applicant's election with traverse of group I, claims 1-4 and 7 directed to the species 1,3-dihydro-3-(imidazol-4-ylmethylene)-5-(pyrid-3-yl)-2H-indolin-one in the reply filed on 6/27/06 is acknowledged.

- 1. Applicant's arguments filed 6/27/06 have been fully considered but they are not persuasive. The restriction is maintained due to the serious burden of search required by the office. The compounds of group I may be found in various art groups depending on the substitutions at R<sup>5</sup> and Ar while the methods of making the compounds can be substantially different in regards to the various substitutions. The process of treating different forms of cancer maybe accomplished via other compounds or compositions as well as concurrently with other forms of treatment.
- 2. The search of the elected species 1,3-dihydro-3-(imidazol-4-ylmethylene)-5-(pyrid-3-yl)-2H-indolin-one was performed and extended to include the species 1,3,-dihydro-3-(imidazol-4-ylmethylene)-5-(acetylamino)-2H-indolin-2-one.

  The restriction is still deemed proper and is therefore made final.
- 3. Claims 5,6 and 8-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Rejoining of the groups I-III will be acceptable at the time of allowance of the elected group I. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/27/06.

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# Claim Rejections - 35 USC § 102

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1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Teng et al. (US 5,792,783).
- 3. Teng et al. (US 5,792,783) teaches of a compound having a cis or trans configuration, that is a modulator of tyrosine kinase signal transduction in order to regulate or inhibit abnormal cell proliferation (abstract; column 12, lines 47-60). R<sub>1</sub> is hydrogen, R<sub>3</sub> is hydrogen, R<sub>2</sub> is oxygen, A is pyrrole or imidazole, and R<sub>4</sub>, R<sub>5</sub>, R<sub>6</sub> and R<sub>7</sub> are independently hydrogen or R<sub>5</sub> is aryl, such as heterocyclic aryl (not excluding pyridyl) or acetylamino NHC(O)R where R is an alkyl group, typically methyl (column 5; column 7, line 10). A pharmaceutically acceptable composition may be prepared in a suitable carrier or with suitable excipients for administration to a human patient (column 15, lines 15-21).

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4. Claims 1-4, 7 are rejected under 35 U.S.C. 102(a) as being anticipated by Teng et al. (US 6,316,429).

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1. Teng et al. (US 6,316,429) teaches of a 2-oxindole below: that is a protein kinase modulator for the treatment of cancer (abstract). Groups A, B, D and E can be carbon, R<sup>2</sup> is hydrogen, R<sup>4</sup>, R<sup>3</sup>, R<sup>5</sup> and R<sup>6</sup> can independently be hydrogen or heteroaryl, such as pyridine and Q is a heteroaryl group, such as imidazole (column 5; column 8, line 39). The composition of the compound may include any pharmaceutically acceptable carrier and be administered in a therapeutically effective amount to a human (column 3, lines 61-67; column 14). A CDK2 inhibition assay was also completed (column 87, lines 10-12).

## Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 1-4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teng et al. (US 6,133,305) in view of Teng et al. (US 5,792,783).

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4. Tang et al. (US 6,133,305) discloses the indole compound below (column 7):

- 5. The indole compound may adopt the cis or trans configuration about the double bond or be a mixture thereof where A is imidazolyl and R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup> are independently hydrogen, alkyl etc. (column 68,lines 52+; column 22, No 25). The compounds are used for modulating the activity of protein kinases such as the serine-threonine kinases, without limitation, CDK2 (column 69, lines 5-16; column 71, lines 47-51). The administration of the drug in a pharmaceutically acceptable carrier to a human patient for the treatment of such diseases as cancer is disclosed (column 75). Tang et al. (US 6,133,305) does not disclose a R<sup>2</sup> heteroaryl or acetylamino substituted oxindole.
- 6. Teng et al. (US 5,792,783) discloses a compound (above) that is a modulator of tyrosine kinase signal transduction in order to regulate or inhibit abnormal cell proliferation (abstract).
- 7. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute R<sup>2</sup> alkyl substituent of the Tang et al. (US 6,133,305) with a pyridyl substitutent of Teng et al. (US 5,792,783) to explore its use as a modulator of the activity of protein kinases such as the serine-threonine kinases, CDK's.

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## Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP July 10, 2006

SUPERVISORY PATENT EXAMINER

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